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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,078	04/07/2006	Jan Bastiaan Bouwstra	0807620.00112	2404

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,078	BOUWSTRA ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *11,12,14,15,17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 are pending.

2. Applicant's election of Group I, Claims 1-10, 13, 16 and 18-20, drawn to a method for the preparation of a vaccine composition in the reply filed on 6/3/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 11, 12, 14, 15 and 17 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-10, 13, 16 and 18-20, drawn to a method for the preparation of a vaccine composition are under consideration in the instant application.

3. Applicant's claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.

4. Applicant's IDS filed on 4/7/06 is acknowledged.

5. Claims 1-10, 13, 16, and 18-20 are objected to because of the following informalities: Claims 1-10, 13, 16, and 18-20 currently begin by reciting "Method" without reciting an appropriate indefinite article "A" for independent claims 1, 13 and 16 or a definite article "The" for dependent claims 2-10 and 18-20. Appropriate correction is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5 and 20 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "said gelatin" recited in claims 5 and 20 has insufficient antecedent basis in the independent claim 1. Claim 1 recites two gelatins (recombinant and synthetic) and "said gelatin" does not specify which gelatin is being referred to.

Moreover, the phrase "essentially similar" is relative and no standard or reference has been provided for comparison of amino acid sequences of gelatin(s).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-10, 13, 16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/34801 (IDS reference) as is evidenced by U.S. Pat. No. 6,685,940B2.

The phrase "the step of taking a measure" in claim 1, lines 2-3 is interpreted as any actions or means to ensure water content remains below 2wt.%.

The '801 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 86, claims 39, 1, 18-19) and the vaccine formulation is lyophilized (p. 61-64). The '801 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa or 9KDa (p. 8, lines 10-15).

Given that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 18-19), the referenced lyophilization results in dryness of the composition, the

claimed "water content remains below 2wt.%" has met and the prevention of recombinant gelatin from crystallization is inherently achieved.

Moreover, the '801 publication teaches that the recombinant gelatin is homogenous (p. 40), claim 2 reciting "homodisperse" ,which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "essentially similar" are included in this rejection.

Claim 13 reciting "bi-modal gelatin" or "multi-modal" gelatin is included in this rejection because the specification p. 11 defines "bi-modal" or "multi-modal" as a composition of more than two or more gelatin peptides (lines 11-15). and the '801 publication teaches "blending of various lots of gelatin mixtures" of heterogeneous mixture of proteins (p. 6).

The '801 publication further teaches that the lyophilized vaccine is stable for 24 months of storage (p. 60) and claims 6-8 reciting "life time is period of storage" are included in this rejection.

Furthermore, claims 9-10 reciting "providing the composition in a sufficiently moisture-tight container" and "providing the composition in a sufficiently air-tight container", respectively, are included in this rejection because the '801 publication teaches a preparation method of vaccine and manufacturing in a kit (p. 67, claims 41-45). The specification of the instant application defines air-tight or moisture tight container as vials (p. 9) and the evidentiary reference '940 patent discloses that a lyophilized protein is packaged in a vial in a kit.

Given that a kit inherently comprises a container and this container should prevent any leakage, therefore, the container is a sufficiently air or moisture tight container. Therefore, the reference teachings anticipate the claimed invention.

10. Claims 1-10, 13, 16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pub. 20030064074 (IDS reference) as is evidenced by U.S. Pat. No. 6,685,940B2.

The phrase "the step of taking a measure" in claim 1, lines 2-3 is interpreted as any actions or means to ensure water content remains below 2wt.%.

The '074 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 23-24, [0221-0232], claims 47, 1, 26-28) and the vaccine formulation is lyophilized (p. [0231]). The '074 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa (p. 3, [0028]).

Given that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 26-28), the referenced lyophilization results in dryness of the composition, the claimed "water content remains below 2wt.%" has met and the prevention of recombinant gelatin from crystallization is inherently achieved.

Moreover, the '074 publication teaches that the recombinant gelatin is homogenous (p. 16, [0162-165]), claim 2 reciting "homodisperse" ,which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "essentially similar" are included in this rejection.

Claim 13 reciting "bi-modal gelatin" or "multi-modal" gelatin is included in this rejection because the specification p. 11 defines "bi-modal" or "multi-modal" as a composition of more than two or more gelatin peptides (lines 11-15). and the '074 publication teaches "blending of various lots of gelatin mixtures" of heterogeneous mixture of proteins ([0020-0021]).

The '074 publication further teaches that the lyophilized vaccine is stable for 24 months of storage (p. 24, [0226]) and claims 6-8 reciting "life time is period of storage" are included in this rejection.

Furthermore, claims 9-10 reciting "providing the composition in a sufficiently moisture-tight container" and "providing the composition in a sufficiently air-tight container", respectively, are included in this rejection because the '074 publication teaches a preparation method of vaccine and manufacturing in a kit (p. 4 [0032], claim 52). The specification of the instant application defines air-tight or moisture tight container as vials (p. 9) and the evidentiary reference '940 patent discloses that a lyophilized protein is packaged in a vial in a kit.

Given that a kit inherently comprises a container and this container should prevent any leakage, therefore, the container is a sufficiently air or moisture tight container. Therefore, the reference teachings anticipate the claimed invention.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
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July 11, 2008

/Yunsoo Kim/
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